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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,069	11/09/2000	Joseph R. Codispoti	MCP-264	3552

7590 07/16/2003

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	28

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/709,069	CODISPOTI, JOSEPH R.	
	Examin r	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication app ars on the cover she t with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-26 and 31-32 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-26 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martindale The Complete Drug Reference 1999 pp 443-444.

The claims are drawn to The claims are drawn to a method of mitigating or treating photophobia and phonophobia associated with a migraine by administering ibuprofen with dependent claims drawn to isomers and salts of ibuprofen.

Martindale's teaches that migraine is characterized by recurrent attacks of headache which typically last 4 to 72 hours and are frequently accompanied by nausea,

vomiting and there may be photophobia and phonophobia. It further teaches that simple analgesics such as NSAIDS (such as ibuprofen) are effective.

It does not specifically teach treating the phonophobia and photophobia specifically.

Since photophobia and phonophobia are part of the symptoms that accompanies a migraine headache, as the ibuprofen alleviates the migraine headache, it would alleviate the symptoms that stem from the migraine itself such as photophobia and phonophobia.

Martindale's does not specifically teach the administration of ibuprofen for a migraine.

The reference recites that NSAIDS (non-steroidal anti-inflammatory drugs) are effective to treat a migraine headache. It would have been made obvious to one of ordinary skill in art at the time the invention was made to treat photophobia and phonophobia associated with a migraine with ibuprofen motivated by the knowledge that ibuprofen is an NSAID drug and hence would be an effective treatment. It would have been obvious to target photo and phonophobia during treatment with ibuprofen disclosed by references (AG) and, since this is well known as taught by reference (AC).

Regarding the specific dosages As anyone of ordinary skill in the art will appreciate, the specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition and age of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the

dosage regimen desired for the composition. Martindale's teaches that the usual dose by mouth varies and the maximum dose is 2.4 grams daily. If a single dose of ibuprofen of 400 mg were to be administered, it would be re-administered every 4 hours. If a single 800 mg dose were administered, it would be re-administered every 8 hours. Therefore it would have been obvious to administer the doses in the claim to treat photophobia and phonophobia associated with a migraine based on the teaching of Martindale's above.

Regarding the isomers of ibuprofen, in general, stereoisomers/optical isomers are obvious from racemic mixtures. As legal authority the examiner cites *In re Adamson and Duffin,* 125 U.S.P.Q. 233. The case sets forth the requirements of patentability with regard to stereoisomers as follows:

1) The existence of a racemate is, in and of itself, sufficient to render obvious any individual stereoisomers contained within; no express suggestion of isomer separation is needed. See the first paragraph on page 235.

2) One skilled in the art expects that individual stereoisomers will differ significantly in physiological/pharmacological activity and toxicity, because living systems are chiral and thus preferentially process stereochemical configurations over others. See page 234, the third full paragraph and page 235, the fifth full paragraph on the page.

S (+)-ibuprofen is known from the recitation of oral formulations of S (+)-ibuprofen of EP 0 753 296 A2; it is taught to be useful for headaches (Page 2, lines 49-52). Consistent with the reasoning of *Adamson*, the existence of that racemate renders

obvious any individual stereoisomers contained within, i.e. the R and S enantiomers recited instantly.

2. Claims 1-26, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diener et al. (AG) in view of Mauskop U.S. Patent No. 5,538,959 A

The claims are drawn to a method of mitigating or treating photophobia and phonophobia associated with a migraine by administering ibuprofen with dependent claims drawn to isomers.

Diener et al (AG) teach a guide to the management and prevention of migraine headaches. Aspirin, **ibuprofen** and paracetamol (acetaminophen) are noted as first-choice analgesics for mild to moderate migraine attacks (page 813, column 2, lines 3-5). Diener et al (U) further teach that migraine is a paroxysmal disorder with attacks of headache, nausea, vomiting, photophobia, phonophobia and malaise (see abstract).

It differs from the instant claims in that it does not explicitly teach targeting photo and phonophobia and it does not teach the isomers.

Since photophobia and phonophobia are part of the symptoms that accompanies a migraine headache, as the ibuprofen alleviates the migraine headache, it would alleviate the symptoms that stem from the migraine itself such as photophobia and phonophobia.

Mauskop (A) teaches the administration of a magnesium salt of an analgesic composition such as ibuprofen (column 2, line 55 to column 3, line 18 and column 7, example 4) and teaches that photo and phonophobia are symptoms normally targeted

during migraine treatment (see abstract). It differs from the instant claims in that it teaches administration of a magnesium salt component. Although Mauskop teaches a magnesium salt, it is clear that the analgesic agent in the composition is ibuprofen (see claim 4)

Regarding the isomers of ibuprofen, in general, stereoisomers/optical isomers are obvious from racemic mixtures. As legal authority the examiner cites *In re Adamson and Duffin,* 125 U.S.P.Q. 233. The case sets forth the requirements of patentability with regard to stereoisomers as follows:

1) The existence of a racemate is, in and of itself, sufficient to render obvious any individual stereoisomers contained within; no express suggestion of isomer separation is needed. See the first paragraph on page 235.

2) One skilled in the art expects that individual stereoisomers will differ significantly in physiological/pharmacological activity and toxicity, because living systems are chiral and thus preferentially process stereochemical configurations over others. See page 234, the third full paragraph and page 235, the fifth full paragraph on the page.

S (+)-ibuprofen is known from the recitation of oral formulations of S (+)-ibuprofen of EP 0 753 296 A2; it is taught to be useful for headaches (Page 2, lines 49-52). Consistent with the reasoning of *Adamson*, the existence of that racemate renders obvious any individual stereoisomers contained within, i.e. the R and S enantiomers recited instantly.

Regarding the specific dosages recited in the claims, as anyone of ordinary skill in the art will appreciate, the specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition and age of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. Martindale's teaches that the usual dose by mouth varies and the maximum dose is 2.4 grams daily. If a single dose of ibuprofen of 400 mg were to be administered, it would be re-administered every 4 hours. If a single 800 mg dose were administered, it would be re-administered every 8 hours. Therefore it would have been obvious to administer the doses in the claim to treat photophobia and phonophobia associated with a migraine based on the teaching of Martindale's above.

It would have been obvious to target photo and phonophobia during treatment with ibuprofen disclosed by references (AG) and, since this is well known as taught by reference (AC).

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Donna Jagoe
Patent Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614

dj
July 10, 2003